# CryoLife Provides Update on 510(K) Premarket Notification for CryoValve SG Decellularized Human Heart Valves

February 6, 2004

ATLANTA, Feb. 6 /PRNewswire-FirstCall/ -- CryoLife, Inc. (NYSE: CRY), a human tissue processing and bio-surgical device company, announced today that the Food and Drug Administration ("FDA") has requested additional information be provided to support the 510(k) premarket notification for the CryoValve SG decellularized human heart valves. The Company plans to work with the FDA to review and address their requirements.

Since February 2003, the Company has been processing tissues without the decellularized SG technology. Revenues from CryoValve SG processed heart valves were not included in the Company's financial guidance for 2004; therefore, the Company's previously announced projection of 12 percent to 18 percent revenue growth remains unchanged.

Founded in 1984, CryoLife, Inc. is a leader in the processing and distribution of implantable living human tissues for use in cardiovascular and vascular surgeries throughout the United States and Canada. The Company's BioGlue(R) Surgical Adhesive is FDA approved as an adjunct to sutures and staples for use in adult patients in open surgical repair of large vessels and is CE marked in the European Community and approved in Canada for use in soft tissue repair and approved in Australia for use in vascular and pulmonary sealing and repair. The Company also manufactures the SynerGraft(R) Vascular Graft, which is CE marked for distribution within the European Community.

Statements made in this press release that look forward in time or that express management's beliefs, expectations or hopes are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These future events may not occur as and when expected, if at all, and, together with the Company's business, are subject to various risks and uncertainties. These risks and uncertainties include that the Company's 2004 revenues may not meet its expectations, that gross margins may not improve in 2004, that SG&A expenses may be higher than projected, that demand for CryoLife preserved tissues may not return to prior levels, the possibility that the FDA could impose additional restrictions on the Company's processing and distribution of tissues, require a recall, or prevent the Company from processing and distributing tissues, that the Company's 510k application for SG processed heart valves may require significant time and expense and may not be cleared on a timely basis or at all, that FDA regulation of the Company's CryoValve SG and CryoVein SG may require significant time and expense, that present and future litigation may be resolved only by substantial payments by the Company in excess of available insurance coverage and amounts to be set aside for products liability cases by CryoLife since the outcomes of products liability securities class action and derivative cases are inherently uncertain, that pending litigation cannot be settled on terms acceptable to the Company, that the Company may not have sufficient resources to pay punitive damages which are not covered by insurance or liabilities in excess of available insurance, the possibility of severe decreases in the Company's revenues and working capital, that over the longer term the Company may not have sufficient capital availability to fund its business, changes in laws and regulations applicable to CryoLife and other risk factors detailed in CryoLife's Securities and Exchange Commission filings, including CryoLife's Form 10-K filing for the year ended December 31, 2002, and the Company's other SEC filings. The Company does not undertake to update its forward-looking statements.

For additional information about the company, visit CryoLife's Web site: http://www.cryolife.com

Contact: Joseph T. Schepers
Vice President, Corporate Communications
(770) 419-3355